

K243301 MapRTMay 19, 2025
213 days to decisionK243301 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k243301/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Oct 18, 2024 |
| Decision date | May 19, 2025 |
| Days to decision | 213 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Vision Rt, Ltd. |
| Location | London, GB |
| Contact | Watheq Al-Hakam |
| Website | http://www.visionrt.com/ |
| 510(k) history | 8 submissions · 8 cleared · 2018-2026 |

Vision RT, Ltd. is a Radiology device manufacturer headquartered in London, UK. The company develops Surface Guided Radiation Therapy (SGRT) solutions that use 3D surface imaging to track patients and improve safety, effectiveness, and efficiency throughout the radiotherapy workflow. Over 3,000 systems are in active clinical use globally. Vision RT has received FDA 510(k) clearances from total submissions since 2018, with no denied submissions. All submissions have focused on Radiology devices. The company's latest clearance was in 2026, confirming active regulatory engag...